Docket No. HRT0287USCNT11

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	John H. Stevens			
Serial No.	:	10/047581	Art Unit	:	3738
Filed	:	October 23, 2001	Examiner	:	C.D. Prone
Title	:	ENDOVASCULAR AORTIC VALVE REPLACEMENT			

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Commissioner for Patents
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APPEAL BRIEF UNDER 37 C.F.R. §41.37

Dear Sir:

This Appeal Brief is filed in response to the Notification of Non-Compliant Brief mailed May 13, 2011 and to the Final Rejection mailed December 8, 2010. A revised Summary of the Claimed Subject Matter is provided herein. The Notice of Appeal was electronically filed on March 8, 2011.

This Brief contains these items under the following headings, and in the order set forth below (37 CFR 1.192(c)):

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1. **Real Party In Interest:**

The real party in interest for this patent application is Ethicon, Inc., U.S. Route 22, Somerville, NJ 08876.

2. **Related Appeals and Interferences:**

There are no related appeals or interferences known to Appellant, the Appellant's legal representative, or the Assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

3. **Status of Claims:**

Claims 15-20, 23, 25-32 and 42-44 stand as finally rejected and are presently appealed.

4. **Status of Amendments:**

No amendments have been filed after the final rejection of December 8, 2010.

5. **Summary of Claimed Subject Matter:**

The present invention, as claimed by independent Claim 15, is directed to a valve for implantation at a desired location within a mammal, comprising:

a flexible sleeve having a proximal end, a distal end and an outside surface (*See e.g.*, Fig. 11; and page 15, lines 1-5 of the original specification);

at least one cusp secured to the sleeve and configured to permit blood flow through the at least one cusp in a single direction (*See e.g.*, Figs. 11 and 12; and page 15, lines 25-36 of the original specification);

at least one ring attached to the outside surface at only the proximal end of the sleeve, the at least one ring being attached to a portion of the sleeve that is not everted, wherein the ring is expandable from a first diameter to a larger, second diameter (*See e.g.*, Figs. 9, 10, 11, and 13 through 15; and page 16, line 13 to page 17, line 2 of the original specification); and

at least one fastener connected to the at least one ring, the at least one fastener extending in a direction radially outward with respect to the sleeve and including at least one

leg (*See, e.g.*, Figs. 11 and 13 through 15; and page 16, lines 22-26 of the original specification).

6. **Grounds of Rejection to be Reviewed on Appeal:**

Whether claims 15-20, 23, 25-32 and 42-44 are unpatentable under 35 U.S.C. 103(a) over 3,657,744 (Ersek) in view of US 5,562,728 (Lazarus).

7. **Argument:**

Claims 15-20, 23, 25-32 and 42-44 are patentable and not obvious under 35 U.S.C. 103(a) over US 3,657,744 (Ersek) in view of US 5,562,728 (Lazarus).

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); see Graham v. John Deere Co., 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. See Graham, 383 U.S. at 17-18, 148 USPQ at 467; Miles Labs, Inc., Inc. v. Shandon Inc., 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir.1993).

Turning to the prior art references that form the basis of the obviousness rejection, the Examiner cites Ersek as the primary reference. Ersek discloses a device and method for fixating a tubular sleeve of deformable material to which a prosthetic member is secured and which is capable of being expanded radially into engagement with surrounding tissue through use of an expansion tool.

The Examiner refers to Figs. 4 and 8 of Ersek. Fig. 4 depicts the fixation devices having "a plurality of longitudinal wire struts 28 separating two expandable and relatively narrow metal

mesh ring sections 29 and 30. A three pronged commissure value is inserted in the upper expandable ring section 29 and secured to the bottom mesh ring 30 circumferentially". Fig. 8 shows "an aortic heart valve 45 in place of a fixation sleeve 16. The rim of valve 45 adjacent the cusps 46 is attached by sutures 47 to the sleeve near one end. A segment of the donor aorta 48 is attached by sutures 49 near the other end of the sleeve 16. The opening 50 in the aorta wall for a coronary artery can be matched with the corresponding opening in the wall of the donee aorta". The Examiner acknowledges that Ersek does not disclose "a fastener member extending from the ring comprising a pair of legs with sharp ends". To overcome the deficiency of Ersek, the Examiner cites Lazarus for teaching "use of a support comprising a plurality of fasteners 151 attached to a zigzag shaped ring comprising a pair of legs having sharp ends (Figures 11-13) in the same field of endeavor for the purpose of piercing and anchoring the device into the surrounding tissue". Based on the foregoing disclosure, the Examiner concludes that "it would have been obvious to one having ordinary skill in the art at the time of the invention was made to combine the fasteners of Lazarus with the device of Ersek in order to provide better attachment to the implant site".

Appellant notes that in addition to the Examiner's acknowledgement that Ersek does not disclose "a fastener member extending from the ring comprising a pair of legs with sharp ends", Ersek's disclosure of rings do not meet Appellant's feature of

"at least one ring attached to the outside surface ***at only the proximal end*** of the sleeve".

In contrast, Ersek discloses in Fig. 4, both proximal and distal rings into which the prosthetic member is inserted and Fig. 8 discloses securement of a prosthetic device within a single ring with securement a several locations within the ring. Clearly, these embodiments do not depict "at least one ring attached to the outside surface ***at only the proximal end*** of the sleeve".

Additionally and in contrast to the claimed invention, Lazarus, only depicts expanding rings at both the distal and proximal end of the sleeve and the expanding rings are not external to

the sleeve and not "***at only the proximal end*** of the sleeve" as required by Appellant's claims.

In the Examiner's final rejection, the Examiner maintained that "considering the claims in light of the broadest reasonable interpretation, the combination does disclose all of the claimed structural components". Appellant submits that the Examiner's rejection is impermissible on at least on two (2) grounds. Firstly, even if one were to accept that all the structural elements are disclosed in the cited references, the Examiner's rejection fails to adequately articulate why it is obvious to combine the cited references in a manner to yield an operable device as claimed by Appellant. In particular, why would one, in view of the cited art, attach the prosthetic member "***at only the proximal end*** of the sleeve" as required by Appellant's claims while the cited art discloses attachment of prosthetic members at multiple locations apart from the proximal end(as noted above). The attachment feature of "at only the proximal end" means exactly that; why the Examiner maintains a 'ring at the distal end is irrelevant to the claim language because the implant discloses separate proximal end rings" is not clear.

Secondly, in the present case, the Examiner relied on reasoning that is unclear why one would combine the cited art in a manner that would leave in some of the structural elements of the prior art while eliminating other structural elements allegedly supported by the combination of Ersek and Lazarus. However, the precise structural elements and their precise relationship to each other as claimed is absent from the cited art and is only present in Appellant's specification (see e.g., Figs 9, 10, and11 and the corresponding description in the specification).

Thus Appellant respectfully submits that the combination of Ersek with Lazarus is improper because it appears that the Examiner relies on information gleaned solely from Appellant's specification. MPEP § 2142 states that "impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of **the facts gleaned from the prior art**" (emphasis added). "'Any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only

knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and **does not include knowledge gleaned only from applicant's disclosure**, such a reconstruction is proper'" (MPEP § 2145(X) (A), quoting *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971), (emphasis added).

Due to the lack of reasoning why one would select and exclude certain elements in the cited art and the fact that the Examiner's rejection is only present on the record in Appellant's specification, it would logically follow that the Examiner's rejection has been improperly gleaned from Appellant's own specification and that the combination of Ersek and Lazarus is an exercise of impermissible hindsight. Accordingly, it is respectfully submitted that the combination is improper and respectfully requested that the rejection be reversed.

Therefore, Appellant submits that the claimed valve is non-obvious and respectfully request the Board to reverse this rejection.

Conclusion:

For the reasons discussed above, Appellant maintains that the Examiner's final rejection of claims 15-20, 23, 25-32 and 42-44 as being unpatentably obvious should be reversed.

Respectfully submitted,

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8. CLAIMS APPENDIX

1-14. (Cancelled)

15. (Appealed) A valve for implantation at a desired location within a mammal, comprising:

a flexible sleeve having a proximal end, a distal end and an outside surface;

at least one cusp secured to the sleeve and configured to permit blood flow through the at least one cusp in a single direction;

at least one ring attached to the outside surface at only the proximal end of the sleeve, the at least one ring being attached to a portion of the sleeve that is not everted, wherein the ring is expandable from a first diameter to a larger, second diameter; and

at least one fastener connected to the at least one ring, the at least one fastener extending in a direction radially outward with respect to the sleeve and including at least one leg.

16. (Appealed) The valve of claim 15, wherein the at least one ring has a height that is less than the distance measured from the proximal end of the sleeve to the distal end of the sleeve.

17. (Appealed) The valve of claim 16, wherein the at least one cusp comprises three cusps attached to the sleeve, the three cusps being configured to open to permit blood to flow through the distal end when subjected to blood flow through the sleeve from the proximal end to the distal end.

18. (Appealed) The valve of claim 17, wherein the three cusps are configured to close to prevent blood flow through the sleeve from the distal end to the proximal end.

19. (Appealed) The valve of claim 17, wherein the valve is configured to have an open position that permits blood to flow through the distal end when blood flows through the

sleeve from the proximal end to the distal end and a closed position to prevent blood from flowing from the distal end to the proximal end of the sleeve.

20. (Appealed) The valve of claim 19, wherein each of the three cusps has at least one side and each of the three cusps are configured to mate along the at least one side with a side of a cusp located adjacent to each of the three cusps when the valve is in the closed position.

21. (Cancelled)

22. (Cancelled)

23. (Appealed) The valve of claim 15, wherein the ring is compressible.

24. (Cancelled)

25. (Appealed) The valve of claim 15, wherein the at least one fastener is for attaching at least the sleeve at a desired location.

26. (Appealed) The valve of claim 25, wherein the at least one fastener comprise a series of legs arranged circumferentially about the ring.

27. (Appealed) The valve of claim 25, wherein the ring has a longitudinal axis and the at least one fastener comprises at least one mounting pin attached to the ring, the mounting pin having two ends offset from one another in the longitudinal direction.

28. (Appealed) The valve of claim 27, wherein the two ends of the at least one mounting pin extend radially outward from the mounting ring.

29. (Appealed) The valve of claim 15, wherein the ring is balloon expandable.

30. (Appealed) The valve of claim 15, wherein the sleeve and cusp are formed of different materials.

31. (Appealed) The valve of claim 15, wherein the at least one cusp comprises one of a homogenic material, an allogenic material and a xenogenic material.

32. (Appealed) The valve of claim 15, wherein the at least one cusp comprises a synthetic material.

33-41. (Cancelled)

42. (Appealed) The valve device of claim 15, wherein the ring has a transport configuration for transporting the valve device to the desired location and a fasten configuration for fastening the valve device at the desired location, and comprising at least one fastener extending from the ring in a direction radially outward with respect to the sleeve when the ring is in the fasten position.

43. (Appealed) The valve device of claim 42, wherein the at least one fastener includes at least one leg having a sharpened distal end.

44. (Appealed) The valve device of claim 43, wherein the sharpened distal end is configured to pierce tissue when the valve device is in the fasten configuration at the desired location.

9. EVIDENCE APPENDIX

None

10. RELATED PROCEEDINGS APPENDIX

None